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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,660	10/07/2004	Bernardus Hedricus Nicolaas Dassen	246152023300	9225

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EXAMINER

DAVIS, BRIAN J

ART UNIT PAPER NUMBER

1621

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/510,660	Applicant(s) DASSEN ET AL.	
	Examiner Brian J. Davis	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/14/05</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Objections

Claim 1 objected to because of the following informalities: for grammatical reasons, in the phrase "...with formula 2..." the word "with" should be deleted and replaced by the word "of." Appropriate correction is required.

Applicant's assistance is respectfully requested in correcting any other minor grammatical and/or spelling errors that may be present in the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear in the text description of the compound of formula 2 why a variable R^3 is listed. There is no variable R^3 in formula 2.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The exact meaning of the terms "chemically [stable]" and "configurationally stable" are unclear because they are undefined. The exact meaning of the term "derivative" is unclear because it is also undefined.

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The remaining claims are also rejected under 35 USC 112, second paragraph, as claims which depend from indefinite claims are also indefinite. *Ex parte Cordova*, 10 USPQ 2d 1949, 1952 (PTO Bd. App. 1989).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Journal of the Pharmaceutical Society of Japan* (1958), 78, p. 1072-1074.

Applicant claims a process for the preparation of the compounds of formula 1 by the hydrogenation of the compounds of formula 2 using a catalyst (Pd) and a mineral acid (claim 1). The dependent claims further refine the process.

Journal of the Pharmaceutical Society of Japan (1958), 78, p. 1072-1074 teaches the reduction of nitriles to a hydroxymethylene group using Pd-C in HCl (abstract), specifically the hydrogenation of compounds VII or VIII to yield compound IX (Chart 1 page 1073).

With specific respect to claims 1 and 8, applicant principally distinguishes over the cited art in that the starting nitrile compound is enantiomerically enriched (so as to yield the corresponding enantiomerically enriched product). However, given the teachings of the cited prior art, one of ordinary skill in the art at the time of the invention would have found such a reaction proceeding from enantiomerically enriched starting materials obvious. This is so, because one of ordinary skill would have immediately recognized that no reaction (and therefore no racemization) would take place at any asymmetric carbon adjacent to the nitrile being reduced. Simply stated: If the reaction

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proceeds without enriched starting materials, it does not yield enriched products; If it begins with enriched starting materials, then it does.

Claims 2, 3, 5-7 and 9 are included in this rejection as they are considered to be mere engineering expediencies – absent some showing of unexpected results. With respect to claims 2, 3 and 5-7, case law is clear on this point: Merely modifying process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. *In re Aller*, 220 F.2d 454, 105 USPQ 233 (CCPA 1955). With respect to claim 9, the particular providence of the starting material cannot impart patentability to a process for its transformation.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Anales de Quimica, Serie C: Quimica Organica y Bioquimica* (1986), 82(1), p. 11-17 (CAPLUS abstract; the examiner notes for completeness of the record that the full paper is also made of record).

The claims have been outlined above.

The abstract of *Anales de Quimica, Serie C: Quimica Organica y Bioquimica* teaches the catalytic hydrogenation using Pd and HCl of a cyano-amino sugar to the corresponding aldehyde-amino sugar. The stereochemistry of the asymmetric carbon adjacent to the nitrile in the starting material is preserved in the product.

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Applicant principally distinguishes over the cited art in that various hydrogen pressures are taught. However, as outlined above, this limitation – absent some showing of unexpected results – cannot impart patentability.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Brian J. Davis
June 25, 2006

BRIAN DAVIS
PRIMARY EXAMINER